



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,173	11/12/1998	DIDIER COMMUNI	VANNA83.001A	5692

27495 7590 05/06/2003

PALMER & DODGE, LLP  
KATHLEEN M. WILLIAMS / STR  
111 HUNTINGTON AVENUE  
BOSTON, MA 02199

EXAMINER
----------

MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 05/06/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Applicant No.	Applicant(s)
	09/077,173	COMMUNI ET AL.
	Examiner	Art Unit
	Joseph F Murphy	1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 20 February 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 70,74-90 and 93 is/are pending in the application.
- 4a) Of the above claim(s) 81-83,85-88 and 90 is/are withdrawn from consideration.
- 5) Claim(s) 76 and 93 is/are allowed.
- 6) Claim(s) 70, 74, 75, 77, 78, 79, 84, 89 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.  
4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: Sequence Comparison A .

## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 11/14/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09077173 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Formal Matters***

Claims 70, 74-90, 93 are pending. Claims 81-83, 85-88, 90 stand withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 70, 74-80, 84, 89, 93 are under consideration. Claims 70, 74-80, 84, 89, 93 were indicated as allowable, but prosecution was suspended due to a potential interference, in Paper No. 22, 1/14/2002. Applicant amended the Sequence Listing in Paper No. 27, 3/3/2003, precipitating a new search. New grounds of rejection are set forth, below.

### ***Claim Rejections - 35 USC § 112 first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 78-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell in culture comprising a polynucleotide with the sequence as set forth in SEQ ID NO: 1, encoding SEQ ID NO: 2, does not reasonably provide enablement for in vivo transfection.

The specification on page 4, lines 18-22 discloses that the nucleic acids of the current invention can be expressed in a wide variety of host cell types, including mammalian cells within a host animal. However, there are no actual or prophetic examples that disclose how to make or use host cells that comprise a DNA sequence as set forth in SEQ ID NO: 1 in an animal. The Examiner cites Eck & Wilson (page 81, column 2, second paragraph to page 82, column 1, second paragraph) who report that numerous factors complicate *in vivo* gene expression which have not been shown to be overcome by routine experimentation. These include, the fate of the DNA vector itself (volume distribution, rate of clearance into the tissues, etc.), the *in vivo* consequences of altered gene expression and protein function, the fraction of vector taken up by the target cell population, the trafficking of the genetic material within cellular organelles, the rate of degradation of the DNA, the level of mRNA produced, the stability of the mRNA produced, the amount and stability of the protein produced, and the protein's compartmentalization within the cell, or its secretory fate, once produced. Since the instant disclosure does not address any of the methods necessary to make a host cell in an animal which comprises the polynucleotide of interest, the claims as written are not enabled.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1646

The preamble of claim 89 is drawn to a method for determining whether a ligand can specifically bind a receptor of SEQ ID NO: 2, while the conclusion of the claim sets forth that the result of the method is to indicate that a ligand is an activator of the receptor. Since the preamble and the conclusion do not correlate, the metes and bounds of the claim are unclear.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 70, 74, 75, 77, 78, 79, 84, 89 are rejected under 35 U.S.C. 102(a) as being anticipated by Nguyen et al. (1995).

Nguyen et al. discloses the cloning and expression of a P2u purinoceptors which binds uridine (page 30845, column 2, first paragraph). The amino acid sequence of the P2u receptor cloned by Nguyen et al. is compared to the amino acid sequence of SEQ ID NO: 2 of the instant claims in Sequence Comparison A, attached. The sequences are 100% identical, thus the polypeptide of Nguyen et al. anticipates the claimed protein o claim70. The nucleic acid sequnce encoding the receptor of Nguyen et al. anticipates claim 74. The nucleic acid se The nucleic acid sequence encoding the P2u receptor of Nguyen et al. was cloned in to an expression vector and transfected into host cells, thus claims 75, 77-79 are anticipated. Nguyen et al. teaches the expression of the encoded protein and the use of that protein in a functional assay to determine the effect of nucleotides on protein function (page 30846, Figure 2), thus claims 84, 89 are anticipated.

Art Unit: 1646

***Conclusion***

Claims 76, 93 are allowable.

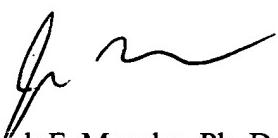
Claims 70, 74, 75, 77, 78, 79, 84, 89 are rejected.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245. The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
April 23, 2003

  
YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600